Practitioner's Docket No. <u>U 013654-2</u>

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Ken-Shwo DAI

Serial No.: 09/964,275

Group No.: 1646

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Filed: September 26, 2001

Examiner.: Stephen L. Rawlings

For: HUMAN NOC2-RELATED GENE VARIANTS ASSOCIATED WITH LUNG CANCER

Commissioner for Patents P. O. Box 1450 Alexandria, VA 22313-1450

TRANSMITTAL OF INFORMATION DISCLOSURE STATEMENT BEFORE MAILING DATE OF EITHER A FINAL ACTION OR NOTICE OF ALLOWANCE (37 C.F.R. 1.97(c))

37 C.F.R. 1.97: "(c) An information disclosure statement shall be considered by the Office if filed after the period NOTE: specified in paragraph (b) of this section, provided that the information disclosure statement is filed before the mailing date of any of a final action under \S 1.113, a notice of allowance under \S 1.311, or an action that otherwise closes prosecution in the application, and it is accompanied by one of:

- The statement specified in paragraph (e) of this section; or (1)
- The fee set forth in § 1.17(p)." (2)

"If a final action or notice of allowance is mailed in an application and later withdrawn, the application will be *NOTE:* considered as not having had a final action or notice of allowance mailed for purposes of considering an information disclosure statement." Notice of April 20, 1992 (1138 O.G. 37-41, 39).

CERTIFICATION UNDER 37 C.F.R. 1.8(a) and 1.10*

(When using Express Mail, the Express Mail label number is mandatory; Express Mail certification is optional.)

I hereby certify that, on the date shown below, this correspondence is being:

MAILING

 \boxtimes deposited with the United States Postal Service in an envelope addressed to the Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450.

37 C.F.R. 1.8(a)

37 C.F.R. 1.10* (Preferred)

 \boxtimes with sufficient postage as first class mail.

Mail Post Office to Address" Mailing Label No (mandatory)

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transmitted by facsimile to the Patent and Trademark Office.

Date: February 10, 2004

Signature

AFFORD J. MASS e of print name of person certifying)

* Only the date of filing (§ 1.6) will be the date used in a patent term adjustment calculation, although the date on any certificate of mailing or transmission under § 1.8 continues to be taken into account in determining timeliness. See § 1.703(f).

Consider "Express Mail Post Office to Addressee" (§ 1.10) or facsimile transmission (§ 1.6(d) for the reply to be accorded the earliest possible filing date for patent term adjustment calculations.

NOTE: 37 C.F.R. § 1.704(d): "A paper containing only an information disclosure statement in compliance with §§ 1.97 and 1.98 will not be considered a failure to engage in reasonable efforts to conclude prosecution (processing or examination) of the application under paragraphs (c)(6), (c)(8), (c)(9), or (c)(10) of this section if it is accompanied by a statement that each item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart application and that this communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the information disclosure statement. This thirty-day period is not extendable."

NOTE: "If information submitted during the period set forth in 37 C.F.R. 1.97(c) with a certification is used in a new ground of rejection on unamended claims, the next Office action will not be made final since in this situation it is clear that applicant has submitted the information to the office promptly after it has become known and the information is being submitted prior to a final determination on patentability by the Office. However, the information submitted with a certification can be used in a new ground of rejection and the next Office action made final, [i]f the new ground of rejection was necessitated by amendment of the application by applicant. Where the information is submitted during this period with a fee, the examiner may use the information submitted, e.g., printed publication or evidence of public use, and make the next Office action final whether or not the claims have been amended, provided that no other new ground of rejection which was not necessitated by amendment to the claims is introduced by the examiner. See MPEP 706.07(a). If a new ground of rejection is introduced that is neither necessitated by an amendment to the claims nor based on the information submitted with the fee set forth in 37 C.F.R. 1.17(p), the Office action shall not be made final. Notice of April 20, 1992 (1138 O.G. 37-41, 39).

WARNING:

"A petition for suspension of action to allow applicant time to submit an information disclosure statement will be denied as failing to present good and sufficient reasons, since 37 C.F.R. 1.97 provides adequate recourse for the timely submission of prior art for consideration by the examiner." Notice of July 6, 1992 (1141 O.G. 63). But see § 103(b) and (c), limited suspension of action in a continued prosecution application (CPA) filed under § 1.53(d) and in a request for continued examination (RCE) under § 1.114.

WARNING:

No extension of time can be had under 37 C.F.R. 1.136(a) or (b) for filing an IDS. 37 C.F.R. 1.97(f):

TIME OF TRANSMITTAL OF ACCOMPANYING INFORMATION DISCLOSURE STATEMENT

- 1. The information disclosure statement transmitted herewith is being filed after three months of the filing date of this national application or the date of entry of the national stage as set forth in § 1.491 in an international application or after the mailing date of the first Office action on the merits, whichever event occurred last but before the mailing date of either:
 - (1) a final action under § 1.113 or
 - (2) a notice of allowance under § 1.311,

whichever occurs first.

STATEMENT OR FEE

2. Accompanying this transmittal is			
		(check either A or B below)	
A.	[]	a statement as specified in 37 C.F.R. 1.97(e).	

B. [X] the fee set forth in 37 C.F.R. 1.17(p) for submission of an information disclosure statement under § 1.97(c). (\$180.00).

OR

	METHOD OF PAYMENT OF FEE		
3.	[X]	Attached is a check in the amount of \$ 180.	
	(Transmittal of Information Disclosure Statement before Mailing Date of Either a Final Action Or Notice of Allowance—page 2 of 3) 6-4	

[]	Charge Account No	in the amount of \$
	A duplicate of this request	is attached.
If any addition	al fees are due, please charg	
Reg. No. 30,08	86	SIGNATURE OF PRACTITIONER CLIFFORD J. MASS
Tel. No.: (212)	708-1890	(type or print name of practitioner)
Customer No.:	00140	P.O. Address
		c/o Ladas & Parry
		26 West 61 st Street
		New York, N.Y. 10023

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<u>INFORMATION DISCLOSURE STATEMENT</u>

Applicant respectfully calls the Examiner's attention to the information attached hereto and listed in the attached PTO Form 1449. Specifically, attached hereto are copies of: (a) a letter from Andrew Chin dated October 28, 2003 (received

CERTIFICATION UNDER 37 C.F.R. 1.8(a) and 1.10*

(When using Express Mail, the Express Mail label number is mandatory; Express Mail certification is optional.)

I hereby certify that, on the date shown below, this correspondence is being:

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37 C.F.R. 1.8(a) 37 C.F.R. 1.10* Xwith sufficient postage as first class mail. as "Express Mail Post Office to Address" Mailing Label No.

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transmitted by facsimile to the Patent and Trademark Office.

Date: February 10, 2004

CLIFFORD J. MASS (type or print name of person certifying) (mandatory)

*WARNING:

Each paper or fee filed by "Express Mail" must have the number of the "Express Mail" mailing label placed thereon prior to mailing, 37 C.F.R. 1.10(b).

Signature

"Since the filing of correspondence under § 1.10 without the Express Mail mailing label thereon is an oversight that can be avoided by the exercise of reasonable care, requests for waiver of this requirement will not be granted on petition." Notice of Oct. 24, 1996, 60 Fed.

Reg. 56,439, at 56,442.

November 4, 2003) calling our attention to a CD-ROM document produced by Dr. Chin entitled "On the preparation and utilization of isolated and purified oligonucleotides"; (b) a hard copy of the initial portion of the text file stored on the CD-ROM that was included with the letter; (c) a letter dated November 7, 2003 which the undersigned sent to the Kathrine R. Everett Law Library; (d) a letter dated November 11, 2003 from Anne Klinefelter of the Kathrine R. Everett Law Library to the undersigned; and (e) an online catalog record of Dr. Chin's CD-ROM that the undersigned recently found on the internet. Also attached hereto is a Computer readable form copy of the CD-ROM provided by Dr. Chin.

Applicant respectfully submits that the attached copy of the CD-ROM satisfies the provisions of 37 CFR 1.98(a)(2) for a legible copy of the information insofar as a computer readable form copy (and not a paper copy) is what has allegedly been deposited with the aforementioned law library. However, if it is considered that the applicable rule requires a computer readable form copy of the information, Applicant hereby petitions for a waiver of the rule and acceptance of the paper copy insofar as, according to Dr. Chin's letter of October 28, 2003, the CD-ROM contains several million oligonucleotides and acceptance of the computer readable form copy would facilitate both submission by the Applicant and consideration of the information by the USPTO. In the event a waiver of the rule is required, Applicant also hereby petitions for waiver of any petition fee insofar as the information is being submitted in connection with nineteen (19) applications of the Applicant and submission of a petition fee for each application would constitute an undue and unfair expense.

With respect to the weight, if any, that should be accorded the information, Applicant respectfully notes that, although it is alleged that the CD-ROM has been cataloged and shelved, it does not appear that the information has been indexed in any meaningful way that would make the information reasonably accessible to the public. In particular, the online catalog record of the CD-ROM, even assuming for the sake of argument that it was available online prior to the filing date of the present application, lists the title, author and subject, but this information does not provide the public with any indication as to what specific oligonucleotides, if any, might be disclosed in the CD-ROM or how to find any particular oligonucleotide that is disclosed. In fact, since the information in the CD-ROM has not been indexed in any meaningful way, the public would not have a ready way to find a particular oligonucleotide from among the millions of oligonucleotides present. Under these circumstances, it is respectfully submitted that the information was not reasonably accessible to the public such that the CD-ROM is not citable as a publication against the present application (see *In re Cronyn*, 13 USPQ 2d 1070, 1072 (Fed. Cir. 1989)).

Respectfully submitted,

CLIFFORD J. MASS LADAS & PARRY

26/WEST 61ST STREET

YEW YORK, NEW YORK 10023

ÆEG. NO.30,086(212)708-1890

FORM PTO-1449 U. S DEPARTMENT OF COMMERCE ATTY. DOCKET NO. SERIAL NO. PATENT AND TRADEMARK OFFICE U 013654-2 09/964,275 INFORMATION DISCLOSURE **APPLICANT** STATEMENT BY APPLICANT Ken-Shwo DAI FILING DATE (Use several sheets if necessary) **GROUP September 26, 2001** 1646 REFERENCE DESIGNATION **U.S. PATENT DOCUMENTS EXAMINER DOCUMENT** FILING DATE IF INITIAL NUMBER DATE NAME APPROPRIATE AA AB AC AD AE AF AG AH Αl AJ AK FOREIGN PATENT DOCUMENTS **DOCUMENT TRANSLATION NUMBER** DATE COUNTRY YES NO ΑL AM AN AO AP **OTHER** (Including Author, Title, Date, Pertinent Dates, Etc.) **ART** "On the preparation and utilization of isolated and purified oligonucleotides" [electronic AR resource], Andrew Chin, allegedly deposited in UNC library on March 14, 2002, date of publication, if any, is in question. AS AT

EXAMINER:

EXAMINER

Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

DATE CONSIDERED